Remarks

Claims 1, 3-7, and 10-26 are pending in the subject application. By this amendment, claims 1, 4-6, and 13 have been amended, claims 3, 7-12, 14-16, and 18-30 have been canceled, and new claims 49-66 have been added. Therefore, claims 1, 4-6, 13, and 49-66 are now before the Examiner for consideration.

The subject invention provides unique and advantageous peptide-based immunotherapeutic agents comprising linear multi-epitope peptides derived from different cedar pollen allergens. Support for these new claims and the amendments to the pending claims can be found throughout the subject specification, for example, at page 30, lines 3-19; pages 8, lines 14-16; page 40, Example 14; page 11, lines 7-15; page 14, lines 3-25; page 15, line 23 through page 16, line 19; and page 42, Example 16. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1, 3-7, 10-13 and 17-26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers *et al.* in view of WO 94/01560 and further in view of Hashiguchi *et al.* or Komiyama *et al.* or WO 94/11512 and Wallner *et al.* Applicants respectfully traverse this grounds of rejection because the cited references, alone or in combination, do not disclose or suggest the specific advantageous products and methods claimed by the Applicants.

It is well-settled law that all the claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants respectfully submit that the cited references, alone or in combination, fail to describe or suggest the motivation to linearly attach two or more Cry j 1 and Cry j 2 T-cell epitopes. Furthermore, when using, as an immunotherapeutic agent, a multi-epitope polypeptide in which T-cell epitope peptides derived from allergens are linearly arranged, it is vital that each of the T-cell epitopes comprising the linear polypeptide can actually function as a T-cell epitope. For example, each of the T-cell epitope peptides should be able to activate its specific T-cell clone. Applicants respectfully submit that the combination of references neither teaches, suggests, nor provides any expectation of success in arriving at the invention as claimed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks and the amendments to the claims, Applicants believe that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this amendment, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address : Saliwanchik, Lloyd & Saliwanchik
A Professional Association
2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/jaj

Attachments: Marked-Up Version of Amended Claims
CPA Request Transmittal Form
Petition for 4-Month Extension of Time
Fee Transmittal Form (in duplicate)

Marked-Up Version of Amended Claims

Claim 1 (Twice Amended):

A peptide-based immunotherapeutic agent comprising a ~~multi-epitope peptide which is a~~ linear polypeptide molecule, wherein said polypeptide: ~~comprising at least two different T-cell epitope peptides that are derived from two or more different allergen molecules and are joined to each other via a peptide bond in an amount effective to prevent or treat allergic symptoms of a patient sensitive to the allergens, wherein~~

~~(1) each of said T-cell epitope peptides reacts with T-cell clones, respectively specific to the T-cell epitope peptides, derived from the patient sensitive to said allergens;~~

~~(2) said multi-epitope peptide reacts dose-dependently with peripheral lymphocytes from the patient sensitive to the allergens;~~

~~(3) said multi-epitope peptide does not substantially react with allergen-specific IgE antibodies of the patient sensitive to the allergen(s); and~~

~~(4) each of said T-cell epitope peptides is restricted by at least two molecules of HLA class II molecules of the patient sensitive to the allergens, selected from the group consisting of DP, DO, and DR antigens.~~

(a) comprises at least two T-cell epitope peptides derived from cedar pollen allergen Cry j 1 and at least two T-cell epitope peptides derived from cedar pollen allergen Cry j 2;

(b) is capable of inducing proliferation of T-cell clones specific to each of said T-cell epitope peptides; and

(c) is capable of dose-dependently inducing proliferation of peripheral lymphocytes from a cedar pollinosis patient.

Claim 4 (Amended):

The peptide-based immunotherapeutic agent of claim 1, ~~wherein~~ further comprising a site that is ~~processed in the antigen presenting cells is inserted between each of the T cell epitope regions~~ cleaved *in vivo*.

Claim 5 (Amended):

The peptide-based immunotherapeutic agent of claim 4, wherein said site ~~that is processed in the antigen presenting cells~~ is an arginine ~~dimer~~ or ~~a~~ lysine dimer.

Claim 6 (Amended):

The peptide-based immunotherapeutic agent of claim ~~3~~1, wherein said ~~peptide~~ polypeptide contains ~~an~~ the amino acid sequence ~~described in any~~ of ~~SEQ ID NO:1, SEQ ID NO:2, or~~ SEQ ID NOs: 1, 2, or 3 or immunostimulatory fragments of SEQ ID NOs: 1, 2, or 3.

Claim 13 (Amended):

The peptide-based immunotherapeutic agent according to ~~of~~ claim 1, wherein each of said ~~T cell~~ T-cell epitopes ~~peptides~~ consists of minimum core sequences ~~with retaining effective T cell reactivity~~ that stimulate T-cell proliferation.